SEP 23 2002 K020848

510(k) Summary of Safety and Effectiveness

The following section is included as required by the Safe Medical Device Act (SMDA) of 1990.

Name: NeoMatrix, LLC
Address: 16 Technology
Suite 118
Irvine, CA 92618
CONTACT PERSON: Kevin Morton

510(k) Summary of Safety and Effectiveness
This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:
Trade Name: NAFD 100
Common Name: Gastroenterology-urology biopsy Instrument
Classification Name: Same

Equivalent Devices:

Manufacturer:	Pro•Duct Health, Inc
Name:	Pro•Duct Catheter
Status:	Currently in commercial distribution
510(k) #	K000135
Manufacturer:	Nastech Pharmaceutical Company, Inc
Name:	Nastech Mammary Aspiration Specimen Cytology Test
Status:	Currently in commercial distribution
510(k) #	K012088
Manufacturer:	Medela, Inc
Name:	Medela's Breast Pump
Status:	Currently in commercial distribution
510(k) #	K950750

Device Description:
The NAFD 100 is intended to non-invasively extract samples of breast duct fluid for breast cancer screening, providing a sample for a "Pap smear" for the breast.

Virtually all breast cancers originate in the epithelial cells that line the walls of fluid ducts that are present in a woman's breast. The case for routine, early breast screening is compelling. By the time a mammogram or manual clinical examination finds an abnormality, the cancerous lesion is already formed. The longer cancer has to develop in the body, it becomes stronger and more difficult to treat.

A screening test using Nipple Aspirate Fluid (NAF) would be similar to a Pap smear, allowing a physician to detect abnormalities before a breast cancer is formed, or to screen for the possible presence of cancer. The routine use of the Pap smear has reduced the incidence of cervical cancer mortality by 70%, through early screening. Breast cancer screening could reasonably be expected to yield the same type of results.

The NAFD 100 incorporates both hardware and disposable components, for use in a physician's office, and was developed to maximize patient comfort, and minimize risk to the patient. The system consists of three components:

System console
Powerhead
Disposable patient interface

Indications for Use:
The NAFD 100 (and its components) is indicated for the collection of nipple aspirate fluid for cytological evaluation. The collected fluid can be used in the determination and/or differentiation of normal versus pre-malignant versus malignant cells.

Biocompatibility:
The materials used to manufacture the NAFD 100 comply with the requirements of ISO 10993-1.

Data Supporting Substantial Equivalence:
NeoMatrix conducted laboratory and fit, form, and performance testing to demonstrate the safe and efficacy of the NAFD 100. Laboratory testing was conducted to evaluate specific device performance parameters. Fit, form and performance testing was conducted to evaluate its use on human subjects. The NAFD 100 has a collection of rate of 54%, which is consistent with other collection methods currently used. From the Journal of the National Cancer Institute published study non-secretors can be expected to average of 40% of those tested.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2002

Neomatrix, LLC
Salvadore F. Palomares
Regulatory Consultant
16 Technology Drive
Suite 118
Irvine, California 92618

Re: K020848
Trade/Device Name: NAFD 100
Regulation Number: 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: July 1, 2002
Received: July 2, 2002

Dear Mr. Palomares:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k):

Device Name: **NAFD 100**

Indications for Use: The NAFD 100 (and its components) is indicated for the collection of nipple aspirate fluid for cytological evaluation. The collected fluid can be used in the determination and/or differentiation of normal versus pre-malignant versus malignant cells.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or _____ Over the Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)

510(K) NUMBER K020848